

In claim 16, line 2, please delete "edges" and substitute therefor --longitudinal ends--.

Please cancel claims 17, 18, and 19 without prejudice.

#### REMARKS

The specification has been amended to correct minor grammatical errors and informalities. Claims 1, 9-11, and 13-16 have been amended to clarify the inventive subject matter. Claims 3-8 and 17-19 have been canceled without prejudice. None of the amendments are considered to be new matter within the meaning of 35 U.S.C. §132. In view of the above amendments and the following remarks, reconsideration is respectfully requested. Amended independent claim 1 now incorporates subject matter previously in claim 8. Amended independent claim 11 now incorporates subject matter previously in claims 19 and 20.

The Examiner's objections to the specification for various typographical errors and informalities has been obviated by the above amendments.

The Examiner has rejected claims 1-23 as being obvious under 35 U.S.C. §103(a) over Myers et al. (WO Patent No. 95/05132) in view of Hubis (U.S. Patent No. 4,478,665). This rejection is respectfully traversed.

Myers discloses an elongate stent having a luminal cover and/or an exterior cover formed of a sheet of expanded polytetrafluoroethylene (ePTFE). The sheet of ePTFE may include uniaxially oriented fibrils which thereby define the longitudinal orientation of the sheet. Myers teaches that the sheet may be applied to the stent so that the fibrils orient transversely to the longitudinal axis of the stent, i.e. circumferentially about the stent. After the cover is applied to the stent, the diameter of the stent may be reduced.

Hubis discloses the use of unsintered ePTFE in the forms of tubes, rods, and sheets for medical purposes.

The present invention recites an elongate stent that is covered by an elongate sheet of unsintered ePTFE. Prior to placement over the stent, the sheet is expanded in its transverse direction which results in the sheet decreasing in length in its longitudinal direction. The transversely expanded sheet is then applied to the stent so that the transverse direction of the sheet aligns with the longitudinal axis of the stent. The longitudinal dimension of the sheet thereby extends circumferentially about the stent. The present invention provides a covered stent which may be radially expanded to a circumference approaching, but not exceeding, the original length of the sheet of unsintered ePTFE as longitudinal expansion of the sheet is limited to its original length. The unsintered ePTFE cover of the present invention thereby defines a limit for radially expanding the covered stent beyond the diameter of the stent when the cover is first applied.

Neither Myers nor Hubis discloses, teaches, or suggests covering a stent at a first diameter with a transversely-expanded and transversely-aligned sheet of unsintered ePTFE so that the sheet can itself expand with the radial expansion of the stent to a second larger diameter. More importantly, there is no teaching in Myers of employing a transversely-expanded and transversely-aligned sheet of ePTFE to limit stent expansion such that the maximum expansion of the sheet defines the maximum expansion of the stent. Myers simply wraps a stent with a sheet of ePTFE without any prior expansion of the sheet. As the sheet of ePTFE in Myers is not transversely expanded prior to being applied to the stent, the Myers device is not able to expand to a diameter that is greater than when the cover is first applied thereto. The maximum diameter of a covered stent formed with a transversely-aligned sheet of ePTFE as taught by Myers is the diameter of the stent at the time that the ePTFE cover is applied thereto.

Unlike Myers, the present invention applies a longitudinally-shortened cover of unsintered ePTFE to a stent at a first diameter so that the stent may expand to a second diameter greater than the first diameter at which the cover was applied. In that the transversely-expanded and transversely-aligned unsintered ePTFE cover of the present invention may be stretched back to its original longitudinal length, it is the cover which thereby further defines the maximum diameter to which the stent may be radially expanded after the cover is applied.

Using the claims of the present invention as a framework, the Examiner states that the Myers device shows:

"a radially expandable stent having a longitudinal stent axis and a stent cover positioned about said stent and being formed of expanded polytetrafluoroethylene (ePTFE), said stent cover being oriented in a first direction and expanded in a second direction transverse to said first so as to decrease the length of said stent cover from its original length, said longitudinal axis of said stent being aligned with said second direction, so that said stent cover is expandable in said first direction to its original length upon said radial expansion of said stent to control radial expanse of said stent . . ." Office Action at paragraph 4(1).

While the Examiner's statement includes many of Applicant's recited elements, such a statement is wholly unsupported by the Myers disclosure. Myers nowhere discloses, teaches, or suggests transversely expanding the cover sheet so as to decrease the length of the cover sheet. Furthermore, Myers nowhere discloses, teaches, or suggests applying such a transversely expanded cover sheet to a stent so as to provide for controlling the radial expansion of the stent.

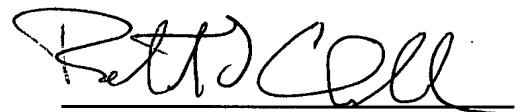
As neither Myers nor Hubis does not disclose, teach, or suggest a covered stent in which an unsintered ePTFE cover determines a maximum radially expanded diameter that is greater than the diameter of the stent when the cover is applied, the present invention is patentably distinguishable therefrom.

In view of the amendments and remarks set forth above, Applicant believes that the claims are now in condition for allowance. Favorable action thereon is respectfully requested.

The Patent and Trademark Office is hereby authorized to charge Deposit Account No. 08-2461 to cover the cost of any additional fees occasioned by this Amendment.

Should the Examiner have any questions with respect to this application, please contact the undersigned counsel.

Respectfully submitted,



Robert F. Chisholm  
Registration No.: 39,939  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
350 Jericho Turnpike  
Jericho, New York 11753  
(201) 331-1700